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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,629	07/05/2001	Shuang Liu	PH-7176	5136

23914 7590 10/28/2003

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EXAMINER

WANG, SHENGJUN

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 10/28/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/899,629

Applicant(s)

LIU ET AL.

Examiner

Shengjun Wang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on April 8, 2003 & July 9, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-92 is/are pending in the application.
- 4a) Of the above claim(s) 1-18, 23-29, 34 and 40-92 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-22, 30-33, 35-39 are is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-18, 40-92 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, Claims 23-29, 34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9.
2. Applicant's election with traverse of invention group V, claims 19-38, and compound A and trihydroxybenzoic acid as the elected species in Paper No. 9 is acknowledged. The traversal is on the ground(s) that group I and V should be examined together since both groups are directed to the same class and subclass. This is not found persuasive because search of group I, is not required for search of group V, further, the search is not limited to patent literature.
3. Claims have been examined insofar as they read on elected invention and species.

The requirement is still deemed proper and is therefore made FINAL.

Double Patent Rejections

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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5. Claims 19-22, 30-33, 35-39 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22, 28-30 of U.S. Patent No. 6537520 in view of Vanderheyden et al. (US 5,679,318) and in further view of Nippon oils (JP 56144060). '520 claims a pharmaceutical composition, or kit, comprising the radionuclide herein. '520 does not expressly claims the stabilizers in the composition or kit. However, Vanderheyden et al. teaches that therapeutical radionuclide compositions generally require the presence of stabilizer. The stabilizer provides enhanced long term stability. One of the well know stabilizer is antioxidant. See, particularly, the abstract. Examples of antioxidants are gentisic acid, or its derivatives, or functionally similar compounds (column 10, lines 43-58). The radionuclide may be ⁹⁰Y (column 5, lines 19-34). Nippon oils teaches gallic acid is a known antioxidant, and are suitable for human consumption. See, particularly, the abstract.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to add antioxidants to the composition in '550 as stabilizers. The employment of the particular antioxidants, e.g., gallic acid and/or gentisic acid is seen to be a selection from amongst equally suitable material and as such obvious, absent evidence to the contrary. Ex parte Winters 11 USPQ 2nd 1387 (at 1388).

Claim Rejections 35 U.S.C. 103

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 19-22, 30-33, 35-39 are rejected under 35 U.S.C. 103(a) as being obvious over Rajopadhye et al (US 6537520) in view of Vanderheyden et al. (US 5,679,318) and in further view of Nippon oils (JP 56144060).

9. The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the

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claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

10. Rajopadhye et al teaches a pharmaceutical composition, or kit, comprising the radionuclide herein. Rajopadhye et al does not expressly teach stabilizers in the composition or kit.

11. However, Vanderheyden et al. teaches that therapeutical radionuclide compositions generally require the presence of stabilizer. The stabilizer provides enhanced long term stability. One of the well know stabilizer is antioxidant. See, particularly, the abstract. Examples of antioxidants are gentisic acid, or its derivatives, or functionally similar compounds (column 10, lines 43-58). The radionuclide may be ^{90}Y (column 5, lines 19-34). Nippon oils teaches gallic acid is a known antioxidant, and are suitable for human consumption. See, particularly, the abstract.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to add antioxidants to the composition in '550 as stabilizers. The employment of the particular antioxidants, e.g., gallic acid and/or gentisic acid is seen to be a selection from amongst equally suitable material and as such obvious, absent evidence to the contrary. Ex parte Winters 11 USPQ 2nd 1387 (at 1388).

12. Claims 19-22, 30-33, 35-39 are rejected under 35 U.S.C. 103(a) as being obvious over Liu et al. in view of Nippon oils (JP 56144060).

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13. Liu teaches method of stabilization of 90Y labeled nuclide conjugate herein (RP697) comprising adding stabilizer to the composition. The stabilizer is antioxidants, particularly, gentisic acid and ascorbic acid. See the abstract.

14. Liu does not teach expressly the employment of gallic acid as an antioxidant.

15. However, Nippon oils teaches that gallic acid is a known antioxidant and are suitable for human consumption. See the abstract.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ gallic acid as an antioxidant. The employment of gallic acid as an antioxidant is seen to be a selection from amongst equally suitable material and as such obvious. Ex parte Winters 11 USPQ 2nd 1387 (at 1388).

16. Claims 19-22, 30-33, 35-39 are rejected under 35 U.S.C. 103(a) as being obvious over Sworin et al. (5,750,088), or Toner et al. (US 5,707,603), in view of Vanderheyden et al. (US 5,679,318) and in further view of Nippon oils (JP 56144060).

17. Sworin et al., or Toner et al. teaches radionuclide conjugates wherein the radionuclide attached to a peptide, or protein, or peptidomimetic moiety through a chelator moiety. See, particularly, the abstract and the claims in Sworn et al.; and the abstract and claims in Toner et al.

18. The primary references do not teach expressly adding stabilizers, such as gallic acid, in the radionuclide conjugate composition.

19. However, Vanderheyden et al. teaches that therapeutical radionuclide compositions generally require the presence of stabilizer. The stabilizer provides enhanced long term stability. One of the well know stabilizer is antioxidant. See, particularly, the abstract. Examples of

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antioxidants are gentisic acid, or its derivatives, or functionally similar compounds (column 10, lines 43-58). The radionuclide may be ⁹⁰Y (column 5, lines 19-34). Nippon oils teaches gallic acid is a known antioxidant, and are suitable for human consumption. See, particularly, the abstract.

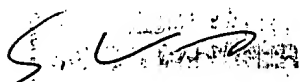
Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to add antioxidants to the radionuclide conjugate compositions disclosed in the primary references as stabilizers. The employment of the particular antioxidants, e.g., gallic acid and/or gentisic acid is seen to be a selection from amongst equally suitable material and as such obvious, absent evidence to the contrary. Ex parte Winters 11 USPQ 2nd 1387 (at 1388).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Patent Examiner



Shengjun Wang
October 24, 2003